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VIA ELECTRONIC FILING
The Honorable Colm F. Connolly
United States District Judge
J. Caleb Boggs Federal Building
844 N. King Street
Unit 31, Room 4124
Wilmington, DE 19801-3555

Re: *Par Pharm., Inc. v. Eagle Pharm., Inc.*, C.A. No. 18-823-CFC

Dear Judge Connolly:

This firm, together with Kirkland & Ellis LLP, represents Defendant Eagle Pharmaceuticals, Inc. ("Eagle") in the above-captioned matter. We write pursuant to the Court's May 11, 2020 Oral Order (D.I. 182) as it applies to Eagle's May 25, 2021 Letter to the Court (D.I. 246) ("May 25 Letter").

Eagle respectfully submits proposed redactions to these letters, along with the supporting Declaration of David Pernock ("Pernock Decl."). The Pernock Declaration is filed contemporaneously hereto. So that this cover letter can remain public, the accompanying confidential Pernock Declaration explains the sensitive nature of Eagle's confidential information in the letters and the harm that Eagle will suffer should that information be disclosed to the public. A version of the May 25 Letter (D.I. 246), highlighted in red to show the specific redactions Eagle seeks, is being filed contemporaneously hereto as as Exhibit A.[1] Eagle explains the bases for its proposed redactions below, as supported by the Pernock Declaration. Eagle respectfully requests that the Court allow the portions of the filings that Eagle has proposed to be redacted to remain under seal.

[1] Exhibit A was filed separately under seal so that this cover letter could be filed publicly.

For the Court's convenience, a public version of the May 25 Letter is attached hereto as Exhibit B.

* * *

The limited information Eagle seeks to redact is the type of competitively sensitive, proprietary information that Eagle safeguards against disclosure. *See* Pernock Decl. ¶¶ 4–7. In particular, Eagle's proposed redactions are tailored to those portions that disclose confidential information regarding the exact date of U.S. Food and Drug Administration's ("FDA") Complete Response Letter ("CRL") to Eagle regarding Abbreviated New Drug Application ("ANDA") No. 211538. Pernock Decl. ¶ 6. Specifically, federal regulations require that the U.S. Food and Drug Administration ("FDA") keep Eagle's ANDA confidential until the application is finally approved. *See* 21 C.F.R. § 314.430; Pernock Decl. ¶ 6. Further, Eagle's business partners that have access to Eagle's ANDA are under a contractual obligation to keep the application and related information confidential. Pernock Decl. ¶ 6.

Courts have recognized that an unapproved ANDA and the information contained therein is "confidential under federal law." *In re Gabapentin Litig.*, 312 F. Supp. 2d 653, 667 n.7 (D.N.J. 2004) (citing 21 C.F.R. § 314.430(b)–(d)); *id.* at 668 (noting that the formulation of a generic drug product is confidential information); *see also Bioavail Labs., Inc. v. Anchen Pharm., Inc.*, 463 F. Supp. 2d 1073, 1083 (C.D. Cal. 2006) (collecting cases discussing confidentiality of the formulation and composition of drug products). Courts have also recognized that the status of an unapproved ANDA is confidential and should be sealed during litigation to prevent disclosure. *See, e.g.*, *Supernus Pharm., Inc. v. TWi Pharm., Inc.*, Civ. No. 15-369, slip op. at 6 (D.N.J. Sept. 21, 2017) (granting generic's motion to seal because "the status of its ANDA with the FDA. . . . is classically protected from public disclosure.").

Moreover, as set forth in the accompanying Pernock Declaration, Eagle respectfully submits that public disclosure of the details concerning the exact date of the FDA's CRL would cause competitive harm to Eagle. *See* Pernock Decl. ¶¶ 7–12; *Littlejohn v. Bic Corp.*, 851 F.2d 673, 678 (3d Cir. 1988) (courts may "deny access to judicial records, for example, where they are sources of business information that might harm a litigant's competitive standing" (citation omitted)).

Eagle is mindful of the Court's desire to permit public access to judicial proceedings, including the public's ability to understand these proceedings. Eagle respectfully submits, however, that the extremely limited nature of the proposed

redactions and the sensitivity of the confidential information set forth in the limited redactions Eagle seeks weighs in favor of redaction, and allowing Eagle to maintain the confidentiality of this information will not affect the public's ability to understand the proceeding. *See, e.g.*, *Supernus*, slip op. at 8 ("[T]he Court agrees with TWi that there is little to no legitimate public interest in the public disclosure of TWi's sensitive information, including . . . the confidential status of its ANDA with the FDA.").

* * *

Eagle respectfully requests that the Court permit these redactions to the public versions of the May 25 Letter (D.I. 246). Counsel for Eagle has conferred with Plaintiff's counsel and Plaintiff does not oppose the redactions sought.

Respectfully,

/s/ Bindu A. Palapura

Bindu A. Palapura

cc: Clerk of the Court (via hand delivery)
Counsel of Record (via electronic mail)

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